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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389

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SUGHRUE, MION, ZINN,
MACPEAK & SEAS, PLLC.
2100 Pennsylvania Avenue N.W.
Washington, DC 20037

EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/14/2002 3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,225	Applicant(s) SHIROYAMA ET AL.
	Examiner Robert M. Joynes	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (US 5294444). Nakamura teaches a transparent cosmetic composition comprising a ceramide, a nonionic surfactant, an ionic surfactant and an aqueous medium (Col. 5, Claim 1). The nonionic surfactant polyoxyethylene hydrogenated castor oil (Col. 3, lines 1-23). The ionic surfactant can be anionic (Col. 3, lines 27-42). The aqueous medium is water (Col. 4, lines 12-16).

Claims 1-3, 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko et al. (WO 98/27958). Kaneko teaches a protective agent for skin and hair comprising a specific ceramide, a surface active agent, a higher fatty acid and a lipid (Page 20, Claims 1-8). The high fatty acids are oleic acid or isostearic acid (Page 7, lines 5-26). The lipid is cholesterol (Page 7, lines 5-26).

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Pillai et al. (US 5476661). Pillai teaches a topical composition for hair, skin or nails comprising a ceramide, nonionic surfactant, ionic surfactant, cholesterol and water (Col. 8, line 56 – Col. 15, line 24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (US 5294444). The teachings of Nakamura are discussed above. Nakamura does not expressly teach the exact concentration ranges recited in the instant claims. The reference further does not teach every ceramide recited in the instant claims.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the concentration ranged of the ingredients of the composition and to substitute one ceramide for another similar ceramide.

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the various types of hosts to receive the composition. One would be motivated to choose one ceramide over another to achieve similar expected results based on availability of each particular ceramide.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura in combination with Murata (US 6348201). The teachings of Nakamura are discussed above. Nakamura does not expressly teach that the anionic surfactant is a higher fatty acid or that other formulations for the ceramides include hair products and bath agents.

Murata teaches a skin hair and bath products comprising sphingolipids, nonionic surfactants, and ionic surfactants (Col. 2, line 10 - Col. 3, line 67; Col. 11,line 33 – Col. 12, line 49). The composition can further contain a ceramide (Col. 12, lines 24-49). Murata further teaches that higher fatty acids, such as oleic and isostearic acid, are known anionic surfactants. The Examples show various formulations for the skin hair and bath (See Examples).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare skin, hair and bath products with ceramides, nonionic surfactants and higher fatty acids in an aqueous medium.

One of ordinary skill in the art would have been motivated to do this to prepare various skin, hair and bath products with the same expected results based on availability of the various ingredients (i.e., based on availability of the different surfactants).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim1-3, 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. (WO 98/27958). The teachings of Kaneko are discussed above. Kaneko does not expressly teach the exact concentration ranges or every specific ceramide recited.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amounts of the ingredients and to substitute one ceramide for another similar ceramide.

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the various types of hosts to receive the composition. One would be motivated to choose one ceramide over another to achieve similar expected results based on availability of each particular ceramide.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko in view of Nakamura. The teachings of both Kaneko and Nakamura are discussed above. Kaneko does not expressly teach that the nonionic surfactant is polyoxyethylene hydrogenated castor oil.

Nakamura, as stated above, teaches that polyoxyethylene hydrogenated castor oil is a known nonionic surfactant that can be used with ceramides in cosmetic compositions.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to substitute one nonionic surfactant for another.

One of ordinary skill in the art would have been motivated to do this to produce a similar composition that is transparent, nonirritating and stable (Nakamura, Col. 2, lines 1-8).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. (US 5476661). The teachings of Pillai are discussed above. Pillai does not expressly teach the exact concentration ranges or every specific ceramide recited.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amounts of the ingredients and to substitute one ceramide for another similar ceramide.

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the various types of hosts to receive the composition. One would be motivated to choose one ceramide over another to achieve similar expected results based on availability of each particular ceramide.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

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Nakamura, as stated above, teaches that polyoxyethylene hydrogenated castor oil is a known nonionic surfactant that can be used with ceramides in cosmetic compositions.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to substitute one nonionic surfactant for another.

One of ordinary skill in the art would have been motivated to do this to produce a similar composition that is transparent, nonirritating and stable (Nakamura, Col. 2, lines 1-8).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600